

**§ 63.366 Reporting requirements.**

(a) The owner or operator of a source subject to the emissions standards in § 63.362 shall fulfill all reporting requirements in §§ 63.10(a), (d), (e), and (f) of subpart A, according to the applicability in Table 1 of § 63.360. These reports will be made to the Administrator at the appropriate address identified in § 63.13 of subpart A of this part.

(1) Reports required by subpart A and this section may be sent by U.S. mail, fax, or by another courier.

(i) Submittals sent by U.S. mail shall be postmarked on or before the specified date.

(ii) Submittals sent by other methods shall be received by the Administrator on or before the specified date.

(2) If acceptable to both the Administrator and the owner or operator of a source, reports may be submitted on electronic media.

(3) Content and submittal dates for deviations and monitoring system performance reports. All deviations and monitoring system performance reports and all summary reports, if required per § 63.10(e)(3)(vii) and (viii), shall be delivered or postmarked within 30 days following the end of each calendar half or quarter as appropriate (see § 63.10(e)(3)(i) through (iv) for applicability). Written reports of deviations from an operating limit shall include all information required in § 63.10(c)(5) through (13), as applicable in Table 1 of § 63.360, and information from any calibration tests in which the monitoring equipment is not in compliance with PS 9 or the method used for temperature calibration. The written report shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. When no deviations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report.

(b) *Construction and reconstruction.* The owner or operator of each source using 10 tons shall fulfill all requirements for construction or reconstruction of a source in § 63.5 of subpart A of this part, according to the applicability in Table 1 of § 63.360, and in this paragraph.

(1) *Applicability.* (i) This paragraph and § 63.5 of subpart A of this part implement the preconstruction review requirements of section 112(i)(1) for sources subject to these emissions standards. In addition, this paragraph and § 63.5 of subpart A of this part include other requirements for constructed and reconstructed sources that are or become subject to these emissions standards.

(ii) After the effective date, the requirements in this section and in § 63.5 of subpart A of this part apply to owners or operators who construct a new source or reconstruct a source subject to these emissions standards after December 6, 1994. New or reconstructed sources subject to these emissions standards with an initial startup date before the effective date are not subject to the preconstruction review requirements specified in paragraphs (b) (2) and (3) of this section and § 63.5(d) (3) and (4) and (e) of subpart A of this part.

(2) After the effective date, whether or not an approved permit program is effective in the State in which a source is (or would be) located, no person may construct a new source or reconstruct a source subject to these emissions standards, or reconstruct a source such that the source becomes a source subject to these emissions standards, without obtaining advance written approval from the Administrator in accordance with the procedures specified in paragraph (b)(3) of this section and § 63.5(d) (3) and (4) and (e) of subpart A of this part.

(3) *Application for approval of construction or reconstruction.* The provisions of paragraph (b)(3) of this section and § 63.5(d) (3) and (4) of subpart A of this part implement section 112(i)(1) of the Act.

(i) *General application requirements.* (A) An owner or operator who is subject to the requirements of paragraph (b)(2) of this section shall submit to the Administrator an application for approval of the construction of a new source subject to these emissions standards, the reconstruction of a source subject to these emissions standards, or the reconstruction of a source such that the source becomes a source subject to these emissions

standards. The application shall be submitted as soon as practicable before the construction or reconstruction is planned to commence (but not sooner than the effective date) if the construction or reconstruction commences after the effective date. The application shall be submitted as soon as practicable before the initial startup date but no later than 60 days after the effective date if the construction or reconstruction had commenced and the initial startup date had not occurred before the effective date. The application for approval of construction or reconstruction may be used to fulfill the initial notification requirements of paragraph (c)(1)(iii) of this section. The owner or operator may submit the application for approval well in advance of the date construction or reconstruction is planned to commence in order to ensure a timely review by the Administrator and that the planned commencement date will not be delayed.

(B) A separate application shall be submitted for each construction or reconstruction. Each application for approval of construction or reconstruction shall include at a minimum:

(1) The applicant's name and address.

(2) A notification of intention to construct a new source subject to these emissions standards or make any physical or operational change to a source subject to these emissions standards that may meet or has been determined to meet the criteria for a reconstruction, as defined in § 63.2 of subpart A of this part.

(3) The address (i.e., physical location) or proposed address of the source.

(4) An identification of the relevant standard that is the basis of the application.

(5) The expected commencement date of the construction or reconstruction.

(6) The expected completion date of the construction or reconstruction.

(7) The anticipated date of (initial) startup of the source.

(8) The type and quantity of hazardous air pollutants emitted by the source, reported in units and averaging times and in accordance with the test methods specified in the standard, or if actual emissions data are not yet available, an estimate of the type and quantity of hazardous air pollutants

expected to be emitted by the source reported in units and averaging times specified. The owner or operator may submit percent reduction information, if the standard is established in terms of percent reduction. However, operating parameters, such as flow rate, shall be included in the submission to the extent that they demonstrate performance and compliance.

(9) Other information as specified in paragraph (b)(3)(ii) of this section and § 63.5(d)(3) of subpart A of this part.

(C) An owner or operator who submits estimates or preliminary information in place of the actual emissions data and analysis required in paragraphs (b)(3)(i)(B)(8) and (ii) of this section shall submit the actual, measured emissions data and other correct information as soon as available but no later than with the notification of compliance status required in paragraph (c)(2) of this section.

(ii) *Application for approval of construction.* Each application for approval of construction shall include, in addition to the information required in paragraph (b)(3)(i)(B) of this section, technical information describing the proposed nature, size, design, operating design capacity, and method of operation of the source subject to these emissions standards, including an identification of each point of emission for each hazardous air pollutant that is emitted (or could be emitted) and a description of the planned air pollution control system (equipment or method) for each emission point. The description of the equipment to be used for the control of emissions shall include each control device for each hazardous air pollutant and the estimated control efficiency (percent) for each control device. The description of the method to be used for the control of emissions shall include an estimated control efficiency (percent) for that method. Such technical information shall include calculations of emission estimates in sufficient detail to permit assessment of the validity of the calculations. An owner or operator who submits approximations of control efficiencies under paragraph (b)(3) of this section shall submit the actual control efficiencies as specified in paragraph (b)(3)(i)(C) of this section.

(4) *Approval of construction or reconstruction based on prior State preconstruction review.* (i) The Administrator may approve an application for construction or reconstruction specified in paragraphs (b)(2) and (3) of this section and §63.5(d)(3) and (4) of subpart A of this part if the owner or operator of a new or reconstructed source who is subject to such requirement demonstrates to the Administrator's satisfaction that the following conditions have been (or will be) met:

(A) The owner or operator of the new or reconstructed source subject to these emissions standards has undergone a preconstruction review and approval process in the State in which the source is (or would be) located before the effective date and has received a federally enforceable construction permit that contains a finding that the source will meet these emissions standards as proposed, if the source is properly built and operated;

(B) In making its finding, the State has considered factors substantially equivalent to those specified in §63.5(e)(1) of subpart A of this part.

(ii) The owner or operator shall submit to the Administrator the request for approval of construction or reconstruction no later than the application deadline specified in paragraph (b)(3)(i) of this section. The owner or operator shall include in the request information sufficient for the Administrator's determination. The Administrator will evaluate the owner or operator's request in accordance with the procedures specified in §63.5 of subpart A of this part. The Administrator may request additional relevant information after the submittal of a request for approval of construction or reconstruction.

(c) *Notification requirements.* The owner or operator of each source subject to the emissions standards in §63.362 shall fulfill all notification requirements in §63.9 of subpart A of this part, according to the applicability in Table 1 of §63.360, and in this paragraph.

(1) *Initial notifications.* (i)(A) If a source that otherwise would be subject to these emissions standards subsequently increases its use of ethylene oxide within any consecutive 12-month

period after December 6, 1996, such that the source becomes subject to these emissions standards or other requirements, such source shall be subject to the notification requirements of §63.9 of subpart A of this part.

(B) Sources subject to these emissions standards may use the application for approval of construction or reconstruction under paragraph (b)(3)(ii) of this section and §63.5(d)(3) of subpart A of this part, respectively, if relevant to fulfill the initial notification requirements.

(ii) The owner or operator of a new or reconstructed source subject to these emissions standards that has an initial startup date after the effective date and for which an application for approval of construction or reconstruction is required under paragraph (b)(3) of this section and §63.5(d)(3) and (4) of subpart A of this part shall provide the following information in writing to the Administrator:

(A) A notification of intention to construct a new source subject to these emissions standards, reconstruct a source subject to these emissions standards, or reconstruct a source such that the source becomes a source subject to these emissions standards with the application for approval of construction or reconstruction as specified in paragraph (b)(3)(i)(A) of this section;

(B) A notification of the date when construction or reconstruction was commenced, submitted simultaneously with the application for approval of construction or reconstruction, if construction or reconstruction was commenced before the effective date of these standards;

(C) A notification of the date when construction or reconstruction was commenced, delivered or postmarked not later than 30 days after such date, if construction or reconstruction was commenced after the effective date of these standards;

(D) A notification of the anticipated date of startup of the source, delivered or postmarked not more than 60 days nor less than 30 days before such date; and

(E) A notification of the actual date of initial startup of the source, delivered or postmarked within 15 calendar days after that date.

(iii) After the effective date, whether or not an approved permit program is effective in the State in which a source subject to these emissions standards is (or would be) located, an owner or operator who intends to construct a new source subject to these emissions standards or reconstruct a source subject to these emissions standards, or reconstruct a source such that it becomes a source subject to these emissions standards, shall notify the Administrator in writing of the intended construction or reconstruction. The notification shall be submitted as soon as practicable before the construction or reconstruction is planned to commence (but no sooner than the effective date of these standards) if the construction or reconstruction commences after the effective date of the standard. The notification shall be submitted as soon as practicable before the initial startup date but no later than 60 days after the effective date of this standard if the construction or reconstruction had commenced and the initial startup date has not occurred before the standard's effective date. The notification shall include all the information required for an application for approval of construction or reconstruction as specified in paragraph (b)(3) of this section and § 63.5(d)(3) and (4) of subpart A of this part. For sources subject to these emissions standards, the application for approval of construction or reconstruction may be used to fulfill the initial notification requirements of § 63.9 of subpart A of this part.

(2) If an owner or operator of a source subject to these emissions standards submits estimates or preliminary information in the application for approval of construction or reconstruction required in paragraph (b)(3)(ii) of this section and § 63.5(d)(3) of subpart A of this part, respectively, in place of the actual emissions data or control efficiencies required in paragraphs (b)(3)(i)(B)(8) and (ii) of this section, the owner or operator shall submit the actual emissions data and other correct information as soon as available but no later than with the initial notification of compliance status.

(3) The owner or operator of any existing sterilization facility subject to this subpart shall also include the

amount of ethylene oxide used during the previous consecutive 12-month period in the initial notification report required by § 63.9(b)(2) and (3) of subpart A of this part. For new sterilization facilities subject to this subpart, the amount of ethylene oxide used shall be an estimate of expected use during the first consecutive 12-month period of operation.

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#### § 63.367 Recordkeeping requirements.

(a) The owner or operator of a source subject to § 63.362 shall comply with the recordkeeping requirements in § 63.10(b) and (c), according to the applicability in Table 1 of § 63.360, and in this section. All records required to be maintained by this subpart or a subpart referenced by this subpart shall be maintained in such a manner that they can be readily accessed and are suitable for inspection. The most recent 2 years of records shall be retained onsite or shall be accessible to an inspector while onsite. The records of the preceding 3 years, where required, may be retained offsite. Records may be maintained in hard copy or computer-readable form including, but not limited to, on paper, microfilm, computer, computer disk, magnetic tape, or microfiche.

(b) The owners or operators of a source using 1 to 10 tons not subject to § 63.362 shall maintain records of ethylene oxide use on a 12-month rolling average basis (until the source changes its operations to become a source subject to § 63.362).

(c) The owners or operators of a source using less than 1 ton shall maintain records of ethylene oxide use on a 12-month rolling average basis (until the source changes its operations to become a source subject to § 63.362).

(d) The owners or operators complying with § 63.363(b) (4) shall maintain records of the compliance test, data analysis, and if catalyst is replaced, proof of replacement.

[66 FR 55585, Nov. 2, 2001]